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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,779	03/08/2001	James E. Hildreth	JHU1710-3	9936

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EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,779	HILDRETH, JAMES E.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,19-30,33-37 and 40-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-15,19-30 and 33-36* is/are allowed.

6)☒ Claim(s) *37 and 40-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's Response dated October 6, 2003

1. In the Response filed October 6, 2003, claims 57-58 were canceled, and claims 4, 37, 52, 55 and 56 were amended. Applicant presented a Terminal Disclaimer. Applicant presented arguments directed to the rejections of claim 37 and 52-56 under 35 U.S.C. 103(a). Claims 1-15, 19-30, 33-37, and 40-56 are pending. An action on the merits of claims 1-15, 19-30, 33-37, and 40-56 is contained herein below.

2. The rejection of claims 1-15, 19-30, 33-37, 40-56 under the judicially created doctrine of obviousness-type double patenting has been rendered moot in view the Terminal Disclaimer filed October 6, 2003.

3. The rejection of claim 37 under 35 U.S.C § 103(a) has been rendered moot in view of the amendment dated October 6, 2003.

4. The rejection of claims 52-56 under 35 USC 103(a) is maintained for the reasons of record as set forth in the Office Action dated July 1, 2003.

5. The rejection of claims 57-58 under 35 U.S.C § 103(a) has been rendered moot in view of the amendment dated October 6, 2003.

6. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Objections/Rejections of Record Set For the in Office Action dated July 1, 2003

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron) in combination with Baert et al. WO 97/18839 (Baert).

Claims 52-56 are directed to a method of reducing the risk of transmission of a sexually transmitted disease comprising contacting the pathogen or cells susceptible to infection by the pathogen with an effective amount of a compositions consisting essentially of a β-cyclodextrin and an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant and a combination thereof.

Bergeron teaches a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other diseases to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The composition acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). The HIV protease and reverse transcriptase inhibitors (alone or in combination) are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Other active agents which may be used include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-

inflammatory agents (column 6, lines 5-24). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The copolymer poloxamer 407 is a chief component of the gel formulation (column 4, lines 15-25). The formulations may include any film-forming component and/or microbicide and/or spermicide and/or any drug and/or liposomes (or other drug carriers) or any combination of these products (column 7, lines 40-50).

Bergeron differs from the instantly disclosed invention in that Bergeron does not limit its disclosure to β-cyclodextrins (drawn to cyclodextrins in general) nor are cyclodextrins taught as the active agent. The selection of a β-cyclodextrin to employ in the method taught by Bergeron would have been obvious to the skilled artisan at the time of the invention in view of the teachings of Baert.

Baert teaches pharmaceutical compositions comprising a β-cyclodextrin (including 2-hydroxypropyl-β-cyclodextrin, see page 13, lines 5-6) and an active ingredient (page 9, lines 24-27). Baert defines the term "active ingredient" as being compounds or mixtures of compounds which are pharmaceutically or therapeutically or cosmetically active for treating humans or animals (page 4, lines 9-16). Active ingredients taught by Baert include loviride which is an art-known anti-retrovirally active compound, particularly useful in treating HIV-infected patients (page 3, lines 35-36). Baert further teaches the ratio of active ingredient to cyclodextrin varies widely and that

ratios of 1/100 [essentially cyclodextrin] to 100/1 may be applied [compositions comprising ~4% (corresponds to 30 mM) included within this range] (page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β-cyclodextrin in the method of Bergeron since Baert teaches using β-cyclodextrin in pharmaceutical compositions which are useful for treating HIV-infected patients. In regards to the "consisting essentially of" claim language, for the purposes of applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". See MPEP 2111.03. The instantly claimed invention is seen to read upon methods for reducing the transmission of a sexually transmitted disease employing a composition comprising a b-cyclodextrin and an additional active agent. Since the Office does not have the facilities for preparing the claimed materials and comparing when with prior art inventions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Response to Arguments

9. Applicant's arguments filed October 6, 2003 have been fully considered but they are not persuasive.

Applicant argues: 1) the art of record does not teach preventing the transmission of a sexually transmitted pathogen by contacting the cell or pathogen with a composition

Applicant argues: 1) the art of record does not teach preventing the transmission of a sexually transmitted pathogen by contacting the cell or pathogen with a composition consisting essentially of β-cyclodextrin and a second composition consisting essentially of a contraceptive, antimicrobial agent, an antiviral agent, a lubricant, or a combination thereof; and 2) the art of record does not teach β-cyclodextrin as an "active agent".

All of the limitations or absolute predictability is not required to establish *prima facie* obviousness. Applicant's arguments are not convincing in view of that which the prior art teaches as a whole. As it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, it is equally obvious to use two separate compositions for an intended purpose when the prior art teaches the use of a single composition containing each of the said singular compositions for the same intended purpose. The intended purpose in the instant case is preventing the transmission of sexually transmitted pathogens. As set forth in the Office Action dated July 1, 2003, the prior art teaches preventing the transmission of sexually transmitted pathogens using a composition comprising β-cyclodextrin and an antimicrobial agent and/or spermicide. The amendment of claim 52 does not obviate the rejection of record.

Regarding applicant's argument that the prior art does not teach β-cyclodextrin as an "active agent", artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art; however, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the

prior art's functioning, does not render the old composition patentably new to the discoverer. Furthermore, products of identical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

In the absence of some proof of a secondary nature to obviate the rejection as set forth in the Office Action dated July 1, 2003, or of some specific limitations which would tip the scale of patentability in the favor of the instantly claimed invention, it would have been obvious to one of ordinary skill in this art at the time of the invention to prevent the transmission of a sexually transmitted pathogen by contacting the cell or pathogen with a b-cyclodextrin and an additional active agent such as an antimicrobial agent and/or spermicide regardless of whether the cyclodextrin and additional active agent are employed in a singular or multiple compositions.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 52-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 52-56 are directed to a method of reducing the risk of transmission of a sexually transmitted disease comprising contacting the pathogen or cells susceptible to infection by the pathogen with an effective amount of a compositions consisting essentially of a β-cyclodextrin and an additional composition consisting essentially of an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant and a combination thereof.

The specification discloses the prevention of the transmission of sexually transmitted pathogens by contacting the cell or pathogen with a composition consisting essentially of β-cyclodextrin or a composition comprising β-cyclodextrin and an additional agent. The support in the specification is not adequate for the claim to the prevention of sexually transmitted pathogens employing two or more compositions wherein one composition consists essentially of β-cyclodextrin and at least one composition consists essentially of an additional active agent. To provide adequate support for the breadth of the claims, applicant would have to provide sufficient evidence that a population of individuals not suffering from a sexually transmitted disease were prevented from acquiring a sexually transmitted disease by contacting the cell or pathogen susceptible to infection with at least two distinct composition wherein the first composition consists essentially of b-cyclodextrin and a second composition consisting essentially of an agent selected from a contraceptive, an agent for treating a

sexually transmitted disease, a lubricant and a combination thereof. No such support is found in the instant disclosure at the time of filing.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 40-45 and 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "consisting essentially of a β-cyclodextrin, a solid substrate and, optionally, an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof" renders the claim indefinite. The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In the instant case, "contraceptives" and "agents for treating a sexually transmitted disease" are notoriously well known for their use in compositions for preventing sexually transmitted diseases and, as such, are seen to have a material affect on the basic and novel characteristics of the composition. Applicant has failed to particularly and distinctly point out what the composition consists essentially of.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 37, 46 and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Trinh et al. US 6,284,231 (Trinh).

Trinh discloses an aqueous odor-absorbing composition consisting essentially of uncomplexed cyclodextrin and optionally a cyclodextrin compatible antimicrobial active, cyclodextrin compatible surfactant, cyclodextrin compatible humectant, hydrophilic perfume providing improved acceptance, or mixtures thereof (column 1, lines 9-30). The term "cyclodextrin compatible" means that the cyclodextrin and the other material, or active, do not substantially interact so as to eliminate the odor controlling ability of the cyclodextrin or the desired effect of the material or active. The cyclodextrin remains uncomplexed while in solution in order to allow the cyclodextrin to absorb various odor molecules when the solution is applied to a surface (column 7, lines 56-65). Beta-cyclodextrin can be present at a level up to its solubility limit of about 1.85% at room temperature which is within the range of suitable cyclodextrin concentrations as taught by applicant (Specification, page 29, lines 2-8).

16. Claims 37 and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacob, "Enhancement of Cyclodextrin Production Through use of Debranching

Enzymes", USDA Agricultural Research Service, Dec. 18, 1998, http://www.nal.usda.gov/ttic/tektran/data/000007/33/0000073334.html (Jacob).

Jacob discloses the production of beta-cyclodextrin in 93% yield. Differences in concentration or temperature do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 40-45 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron) in combination with Baert et al. WO 97/18839 (Baert).

Claims 40-45 and 50-51 are drawn to a composition consisting essentially of a b-cyclodextrin, a solid substrate and, optionally, an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof. Claims 41 and 44-45 limit the solid substrate. Claims 42-43 limit the physical form of the composition. Claims 50-51 limit the amount of cyclodextrin in the composition.

Bergeron teaches a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other diseases to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The composition acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the

pathogen (column 3, lines 34-67). The HIV protease and reverse transcriptase inhibitors (alone or in combination) are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Other active agents which may be used include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The copolymer poloxamer 407 is a chief component of the gel formulation (column 4, lines 15-25). The formulations may include any film-forming component and/or microbicide and/or spermicide and/or any drug and/or liposomes (or other drug carriers) or any combination of these products (column 7, lines 40-50).

Bergeron differs from the instantly disclosed invention in that Bergeron does not limit its disclosure to β-cyclodextrins (drawn to cyclodextrins in general) nor are cyclodextrins taught as the active agent. The selection of a β-cyclodextrin to employ in the method taught by Bergeron would have been obvious to the skilled artisan at the time of the invention in view of the teachings of Baert.

Baert teaches pharmaceutical compositions comprising a β-cyclodextrin (including 2-hydroxypropyl-β-cyclodextrin, see page 13, lines 5-6) and an active ingredient (page 9, lines 24-27). Baert defines the term "active ingredient" as being compounds or mixtures of compounds which are pharmaceutically or therapeutically or cosmetically active for treating humans or animals (page 4, lines 9-16). Active

ingredients taught by Baert include loviride which is an art-known anti-retrovirally active compound, particularly useful in treating HIV-infected patients (page 3, lines 35-36). Baert further teaches the ratio of active ingredient to cyclodextrin varies widely and that ratios of 1/100 to 100/1 may be applied [compositions comprising ~4% (corresponds to 30 mM) included within this range] (page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β-cyclodextrin in the composition of Bergeron since Baert teaches that β-cyclodextrins are employed in pharmaceutical compositions which are useful for treating HIV-infected patients. The prior art use of β-cyclodextrin in compositions designed to prevent the transmission of a sexually transmitted diseases provides ample motivation and a reasonable expectation of success for doing so.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In the instant case, "contraceptives" and "agents for treating a sexually transmitted disease" are notoriously well known for their use in compositions for preventing sexually transmitted diseases and, as such, are seen to have a material affect on the basic and novel characteristics of the composition. The ambiguity of the claim language would prevent one of ordinary skill in the art from ascertaining the metes and bounds of the instant invention. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. Since the Office does not have the facilities for preparing the claimed materials and comparing when with prior art inventions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

21. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trinh et al. US 6,284,231 (Trinh) in combination with Bergeron et al. U.S. Patent 6,068,851 (Bergeron).

Claim 47 is drawn to a pharmaceutical composition consisting essentially of a β-cyclodextrin formulated in a suppository, a film, a sponge, a condom, a bioadhesive polymer, a diaphram, a glove, a pellet, a tablet, or a tampon.

Trinh teaches an aqueous odor-absorbing composition consisting essentially of uncomplexed cyclodextrin and optionally a cyclodextrin compatible antimicrobial active, cyclodextrin compatible surfactant, cyclodextrin compatible humectant, hydrophilic perfume providing improved acceptance, or mixtures thereof (column 1, lines 9-30). The term "cyclodextrin compatible" means that the cyclodextrin and the other material, or active, do not substantially interact so as to eliminate the odor controlling ability of the cyclodextrin or the desired effect of the material or active. The cyclodextrin remains uncomplexed while in solution in order to allow the cyclodextrin to absorb various odor molecules when the solution is applied to a surface (column 7, lines 56-65). Beta-

cyclodextrin can be present at a level up to its solubility limit of about 1.85% at room temperature which is within the range of suitable cyclodextrin concentrations as taught by applicant (Specification, page 29, lines 2-8).

Trinh differs from the instantly claimed invention in that Trinh does not teach compositions formulated into a suppository, a film, a sponge, a condom, a bioadhesive polymer, a diaphram, a glove, a pellet, a tablet, or a tampon; however, to do so would have been obvious to one of ordinary skill in the art at the time of the invention when viewed in light of Bergeron.

Bergeron teaches a composition for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). The composition acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component [implicit teaching of compositions formulated into a film] and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). HIV protease and reverse transcriptase inhibitors (alone or in combination) are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate a cyclodextrin-containing composition into film since Bergeron teaches compositions containing a cyclodextrin and a film-forming component for preventing the transmission of sexually transmitted diseases. Reciting an old composition in a new physical form only incidentally related to its unobvious utility will

not impart patentability thereto. Where the utility of the new form of the old material is no different that that of the old form, the new form is ordinarily unpatentable over the old. In the instant case, cyclodextrin-containing materials are known in the art as being useful for preventing the transmission of sexually transmitted diseases when formulated into a composition containing a film-forming component. Indeed, the prior art provides ample motivation for formulating cyclodextrin-containing materials into films or the like, and thus renders the instantly claimed composition prima facie obvious.

Conclusion

22. Claims 1-15, 19-30, 33-37, and 40-56 are pending. Claims 37 and 40-56 are rejected. Claims 1-15, 19-30, and 33-36 are allowed.

Allowable Subject Matter

23. The instantly claimed method for preventing the transmission of a sexually transmitted pathogen employing a composition consisting essentially of β-cyclodextrin is not taught or suggested in the prior art. Bergeron et al. U.S. Patent 6,068,851 (Bergeron) is seen as the closest prior art. Bergeron teaches a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases. The formulation acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen. Inhibitors of HIV protease and reverse

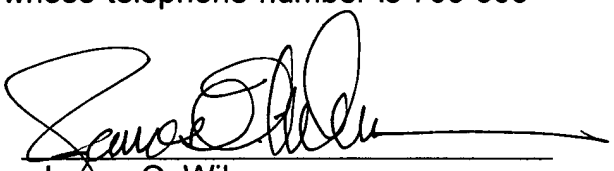
agent for the preventing the transmission of the pathogen. One of ordinary skill in the art at the time of the invention would not have had a reasonable expectation of success in preventing the transmission of a sexually transmitted pathogen employing compositions consisting essentially of β-cyclodextrin as the sole active agent. Bergeron is seen to teach away from the instantly claimed method in that Bergeron only teaches compositions employing a microbicide, spermicide, and/or other drug effective against the pathogen wherein cyclodextrin is not required. Furthermore, Bergeron does not explicitly or implicitly teach β-cyclodextrin as an active agent for the prevention of sexually transmitted pathogens.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Patrick T. Lewis, PhD
Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
December 18, 2003